

PATENT

Application No.: 10/665,307

Filed: September 18, 2003

REMARKS

Claims 1-5 and 7-26 are pending. Claims 1, 2, 14, 15, 17 and 22 have been amended. Support is found throughout the specification. See, for example, paragraphs [0006], [0244] and Examples 1 and 2 of US Pub. No. US 2004/0043430 A1. No new matter is introduced by way of this amendment.

Interview Summary

Applicants kindly thank the Examiner for the courtesy of a telephonic interview on January 22, 2008. Applicants discussed the rejections of record, technical problems with the January 4, 2008 Response to the Office Action of October 5, 2007, and support for the amendments in the January 4, 2008 Response. Agreement was not reached.

Claim Rejection under 35 USC §§ 101 and 112

Claims 1-5 and 7-26 are rejected under 35 USC §§ 101 and 112 as failing to provide a utility. The Office Action suggested that the claims lacked patentable utility because the "claims do not recite any particular improvement or resultant characteristic that is imparted to proteins generated by the instant method or how analysis of the resultant secondary protein sequences would be used to yield any useful information." While Applicants respectfully disagree, it is noted that the claims have been amended in an effort to further prosecution of this application. Applicants submit that the claims recite a method that results in the generation of a secondary library of amino acid sequences that are selected based on at least one desired characteristic relative to a target protein. The claimed method results in synthesizing and screening of a variant protein for the at least one desired characteristic. Thus, the claimed methods do set forth an improvement and an indication of how the analysis of the secondary protein sequences would be used to yield useful information. Accordingly, Applicants respectfully submit that the claims are patentable. Applicants respectfully request the Examiner to withdraw the rejections under 35 USC §§ 101 and 112.

Written Description Requirement under 35 USC § 112, first paragraph

In response to a question raised during the telephonic interview, Applicants respectfully submit that the amendment of "screening for said at least one desired characteristic" fully complies with the written description requirement. As stated in the MPEP, § 2106 (V)(B)(1):

For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-67, 43 USPQ2d 1398, 1404-05 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). The claimed invention subject matter need not be described literally, i.e., using the same terms, in order for the disclosure to satisfy the description requirement. Software aspects of inventions, for example, may be described functionally. See *Robotic Vision Sys. v. View*

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Eng'g, Inc., 112 F.3d 1163, 1166, 42 USPQ2d 1619, 1622-23 (Fed. Cir. 1997); *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997); *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1537-38, 25 USPQ2d 1241, 1248-49 (Fed. Cir. 1992). See MPEP § 2163 for further guidance with respect to the evaluation of a patent application for compliance with the written description requirement.

As shown in Examples 1 and 2 and paragraphs [0003], [0006], and [0244] of US Pub. No. US 2004/0043430 A1, Applicants were in possession and have described screening the secondary libraries of the invention. As an example, paragraph [0006] states, "It is an object of the present invention to provide computational methods for prescreening sequence libraries to generate and select secondary libraries, which can then be **made and evaluated experimentally.**" (Emphasis added). "Making and experimentally evaluating" is another way of saying "synthesizing and screening." The MPEP also states at § 2163 (I):

The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). "The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005)....

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998)....

MPEP § 2163 (II)(2) states:

Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

One of skill in the art will recognize that Applicants were in possession of the invention, as currently claimed, at the time of filing. The limitation of screening a library of proteins for a desired characteristic was in the possession of one of skill in the art at the time of filing. Applicants specifically pointed out the limitation of screening a secondary library in the specification, as well as demonstrated several favorable characteristics screened for in the Examples. Applicants thus respectfully submit the claims as currently amended meet the Written Description requirement.

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Conclusion

Applicants believe the present application is in condition for allowance. Early favorable communication thereof is respectfully requested. Please direct any calls in connection with this application to the undersigned at (415) 442-1216.

While Applicants believe that no other fees are due at this time, the Commissioner is authorized to charge any fees, including extension fees or any other relief that may be required, in connection with this reply to Deposit Account 50-0310 (Docket No.: 67461-5041US06).

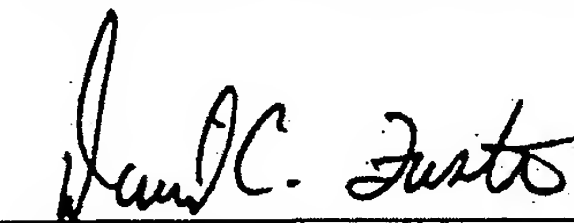
The undersigned is an attorney or agent of record.

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Dated: February 5, 2008

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Filed Under 37 C.F.R. 1.34